

AWARD NUMBER: W81XWH-14-1-0143

TITLE: Comparing Web, Group and Telehealth Formats of a
Military Parenting Program

PRINCIPAL INVESTIGATOR: Abigail Gewirtz, Ph.D.

CONTRACTING ORGANIZATION: University of Minnesota
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14. ABSTRACT <p>By December of 2012 approximately 2.2 million US military personnel will have served one or more times in Iraq or Afghanistan in support of Operations Enduring Freedom, Iraqi Freedom (OEF/OIF), and New Dawn (Institute of Medicine/IOM 2013). Stress associated with family separation, combat, and reintegration is extremely disruptive for parents and children. Returning service members and their families are particularly vulnerable during the reintegration period post-deployment. Risks include increases in stress, anxiety and depression, PTSD, and substance use and abuse. These outcomes lead to disruptions in interactions between parents, children, and spouses, increasing risk for children's emotional, behavior problems, and substance use.</p> <p>The overarching goal of our study is to address existing gaps and identified National Guard Reserve (NGR) needs that will inform the portability and access of NGR families to evidence-based programs by conducting a three-group, two-site randomized trial to test the comparative effectiveness of three ADAPT delivery approaches for 360 reintegrating NGR families randomly assigned to: (i) ADAPT group-based; (ii) ADAPT individualized web-facilitated; or (iii) ADAPT self-directed online. Families will complete pre-intervention baseline (BL) assessment (pre-test) and three post-test assessments at 6, 12- and 24 months. We hypothesize that NGR families in both the ADAPT group-based condition and the ADAPT individualized web-facilitated condition will show greater pre-post improvements in observed parenting, and parent, child, and couple functioning relative to the self-directed online condition and the ADAPT group-based condition will be equally effective as the individualized ADAPT web-facilitated condition.</p>					
15. SUBJECT TERMS Parenting, military, comparative effectiveness, children, randomized trial, prevention					
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1. INTRODUCTION:

By December of 2012 approximately 2.2 million US military personnel will have served one or more times in Iraq or Afghanistan in support of Operations Enduring Freedom, Iraqi Freedom (OEF/OIF), and New Dawn (Institute of Medicine/IOM 2013). Stress associated with family separation, combat, and reintegration is extremely disruptive for parents and children. Returning service members and their families are particularly vulnerable during the reintegration period post-deployment. Risks include increases in stress, anxiety and depression, PTSD, and substance use and abuse. These outcomes lead to disruptions in interactions between parents, children, and spouses, increasing risk for children's emotional, behavior problems, and substance use. While the need to support military families has been identified as an important national priority by numerous government-supported task forces, major gaps in effectively serving military families remain. First, most intervention and outreach efforts are guided by models lacking empirical support or programs lacking a strong theoretical background. A large majority of evaluations do not include rigorous methodology, randomization, implementation in real world settings, or long-term follow up. Second, many barriers remain for military families not living near a military competent treatment center or Veterans Administration Medical Center. The After Deployment Adaptive Parenting Tool (ADAPT) study is the only study to date with preliminary evidence from an RCT. We propose to address existing gaps and identified NGR needs that will inform the portability and access of NGR families to evidence-based programs.

Specific Aim 1: Evaluate the usability and acceptability of the individualized web-facilitated ADAPT condition with 5 military families, and an expert stakeholder panel. Compare recruitment, retention, and satisfaction with the web-facilitated condition with existing data on the ADAPT group-based and self-directed conditions.

Specific Aim 2: Conduct a three-group, two-site randomized trial to test the comparative effectiveness of three ADAPT delivery approaches for 360 reintegrating NGR families randomly assigned to: (i) ADAPT group-based; (ii) ADAPT individualized web-facilitated; or (iii) ADAPT self-directed online. Families will complete pre-intervention baseline (BL) assessment (pre-test) and three post-test assessments at 6, 12- and 24 months.

Specific Aim 3: Evaluate generalizability of ADAPT effectiveness across three intervention delivery approaches using intent to treat (ITT) analyses. We will specifically test the value-added impact of group-based delivery relative to web-facilitated and web self-directed approaches. Comparative effectiveness will be tested by specifying a non-equivalence hypothesis for group-based and web-facilitated relative to self-directed only.

- **Aim 3 Hypothesis 1.** NGR families in both the ADAPT group-based condition and the ADAPT individualized web-facilitated condition will show greater pre-post improvements in observed parenting, and parent, child, and couple functioning relative to the self-directed online condition.
- **Aim 3 Hypothesis 2.** In testing intent to treat comparative effectiveness, the ADAPT group-based condition will be equally effective as the individualized ADAPT web-facilitated condition

2. KEYWORDS:

Parenting, military, comparative effectiveness, children, randomized trial, prevention program

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Task 1: Prepare University of Minnesota IRB and DOD regulatory documents for review and approval.

- 1a. Finalize human subjects protocol and consent documents for pilot group (N=5 families), and randomized controlled trial (N=360 families).

Task 2: Recruit for open positions (coordinator in MI and MN) and process paperwork to hire all project staff.

Task 3: Obtain U of MN IRB approval (Y1 Mos. 1-3)

Task 4: Obtain DoD HRPO approval (Y1 Mos. 1-6)

Aim 1: *Examine the usability and acceptability of the delivery format for the individualized web-facilitated ADAPT:*

Task 5: Systematically modify ADAPT web-facilitated delivery format in consultation with Advisory Group

- 5a. Convene expert panel (Y1 Mos. 4-5)

- 5b. Refine existing ADAPT materials (online/Google Hangout and manual) (Y1 Mos 1-10)

- 5c. Conduct pilot group to test usability (Y1 Mos. 6-9)

- 5d. Analyze pilot group data to inform materials and RCT (Y1 Mos. 9-10)

Task 6: Train facilitator staff in MI and MN to deliver ADAPT group with fidelity (Y1 Mos 7-12)

Aim 2. Conduct a three-group, two-site randomized trial to test the comparative effectiveness of ADAPT delivery approaches.

Task 7: Recruit three cohorts of 60 families per cohort in Minnesota (20 online, 20 group, 20 web-facilitated) and 60 families per cohort in Michigan (20 online, 20 group, 20 web-facilitated) for a total of 360 families (120 per cohort). (Y1 Mos. 11-12; Y2 Mos. 13-24; Y3 Mos. 25-26)

- 7a. Obtain informed consent and complete baseline and subsequent assessments of adult adjustment, observational measures of parenting, measures of child, and couple adjustment. (Y1 Mos 11 – Y5 Mo 50)

- 7b. Randomly assign families to online ADAPT, web-facilitated ADAPT or group ADAPT; families invited to program (Cohort 1: Y1 Mos. 11-13; Cohort 2: Y2 Mos. 18-20; Cohort 3: Y2 Mos. 24 - Y3. Mo. 26)

- 7c. Assess parent satisfaction ratings via questionnaires at end of each session (Y1 Mo. 12 – Y3 Mo. 30)

Aim 3. Test the generalizability of ADAPT effectiveness across three delivery approaches using intent to treat (ITT) analyses

Task 8. Clean and analyze outcome data to examine differential effectiveness (Y2 Mo 24 – Yr 5 Mo 60)

Quarterly Enrollment Targets (# of families): Yr 1: Q1=0 ; Q2 =0 ; Q3 =5 ; Q4 =68 ; Yr 2: Q1=78 ; Q2 =78 ; Q3 =78 ; Q4 =78 ; Yr 3: Q1= 0; Q2 =0 ; Q3 =0 ; Q4 =0 ; Yr 4: Q1=0 ; Q2 =0 ; Q3 =0 ; Q4 =0

What was accomplished under these goals?

Task 5:

- We completed 2 pilot test cases for telehealth and incorporated feedback into final study materials.

Task 6:

- We completed a second training for our first cohort of MN facilitators, an initial telehealth training for MN facilitators, and a first training for MI facilitators. We are preparing for the first training of the second cohort of MN and MI (East side) facilitators.

Task 7:

- We recruited 95 families in MN and 25 families in MI (see appended recruitment graph).
- We boosted our recruitment campaign through radio shows and attending 26 military outreach events.
- Interventions were started in both MN and MI. We completed the first MN in-person groups, started MI in-personal groups, started both MN and MI telehealth families, and started a MN online cohort.
- Both MN and MI in-home technicians have completed necessary training and are completing in-home assessments.
- We commenced T2 (6 month) data collection for MN families completing the intervention.
- We are preparing for T3 (1 year) data collection for MN families.

Task 8:

- A formal data management plan has been established and is reviewed frequently for integrity and improvement.

What opportunities for training and professional development has the project provided?

Two 4-day ADAPT trainings were provided to facilitators delivery the group intervention. One 2-day ADAPT training was provided to facilitators delivery the telehealth intervention. Ongoing bi-weekly coaching sessions were also provided to trained facilitators on an individual basis.

How were the results disseminated to communities of interest?

Nothing to report

What do you plan to do during the next reporting period to accomplish the goals?

Our main goals for the third year are (1) boost recruitment in both MN and MI, (2) deliver additional interventions in both MN and MI, and (3) collect 6 month and 1 year data from families who have completed the intervention.

Boost recruitment in MN and MI

- We plan to increase our outreach efforts in both states through community mapping.
- We will collaborate with additional military and community partners in both states to identify potential participants.
- We will institute a MI Advisory Board to solicit input on outreach and recruitment strategies.
- We will initiate mailing letters to MI veterans through the VA.

Deliver additional interventions in MN and MI

- We will complete the second facilitator training this summer (August 1-4, 2016) that will allow additional intervention groups to commence.

Collect 6 month and 1 year data

- We will continue collecting T2 (6 month) data.
- We will review and implement T3 (1 year) data collection processes.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

We delayed the timeline, in discussion with our program officer, because of the timing of the award: beginning recruitment at Month 11 would have meant starting our interventions in the summer, which is a difficult time to deliver programming for families because of summer disruptions to family routines and schedules. Recruitment was scheduled to begin in early July 2015, with study program delivery in the fall. Study recruitment began summer of 2015. It took a number of months to get enough participants in each condition in order to deliver the intervention. To avoid challenges with scheduling and participation during major holidays, the first interventions started January 2016.

Changes that had a significant impact on expenditures

- Former Project Manager Nonyelum Harcourt left in January 2016 and was later replaced by Amy Majerle.
- We hired a 50% time assistant in Michigan starting May 3, 2016.
- The addition of the Selfridge, MI area as a recruitment site resulted in the need for additional personnel and travel funds.
- Our subject payment expenditures have been delayed due to the delay in recruitment and intervention delivery.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals.

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report

6. PRODUCTS:

- **Publications, conference papers, and presentations**
Report only the major publication(s) resulting from the work under this award.

Journal publications.

Nothing to report

Books or other non-periodical, one-time publications.

Nothing to report

Other publications, conference papers, and presentations.

Nothing to report

- **Website(s) or other Internet site(s)**

Our study website which is used for recruiting and will be used to disseminate study results is ADAPT4U.umn.edu

- **Technologies or techniques**

In collaboration with a software engineer, we have developed a mindfulness app to deliver practice exercises more easily than through our web portal and more specifically to carefully track usage. The app was alpha and beta tested but will not be used with subjects until IRB and HRPO approvals are applied for and received (summer 2016).

- **Inventions, patent applications, and/or licenses**

Nothing to report

- **Other Products**

Our study curriculum will be utilized for intervention.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Gewirtz, Abigail
Project Role:	PI
Person months worked:	1.0 month
Contribution to Project:	Overall study oversight and strategic decision making on research methodology. Ensuring study outcomes are achieved
Funding support:	This award
Name:	Harcourt, Nonyelum
Project Role:	Project Manager
Person months worked:	6.0 months
Contribution to Project:	Overall management of study tasks and personnel. Tracking study milestones and designing study data collection tools
Funding support:	This award
Name:	Majerle, Amy
Project Role:	Project Manager
Person months worked:	2.0 months
Contribution to Project:	Overall management of study tasks and personnel. Tracking study milestones and designing study data collection tools
Funding support:	This award
Name:	Molly Willer
Project Role:	Intervention Coordinator
Person months worked:	3.0 months
Contribution to Project:	Ensures training of intervention facilitators and fidelity of implementation of study interventions
Funding support:	This award (2 months) plus leveraged non-sponsored funds (1 month)
Name:	Fletcher, Mark
Project Role:	Project Coordinator
Person months worked:	12.0 months
Contribution to Project:	Management of study tasks for Michigan
Funding support:	This award
Name:	Tiede, Shauna
Project Role:	Assessment Coordinator
Person months worked:	6.0 months
Contribution to Project:	Overall management of the in-home assessment of the participants. Responsible for creating study manuals and training study technicians.
Funding support:	This award

Name:	Aneta Pszczola
Project Role:	Assessment Technician
Person months worked:	5.0 months
Contribution to Project:	Completes in-home assessments and initiates online data collection at post-intervention time points
Funding support:	This award
Name:	Adam Vanderwal
Project Role:	Facilitator
Person months worked:	1.0 month
Contribution to Project:	Delivers intervention to study participants
Funding support:	This award
Name:	Darlene Wetterstrom
Project Role:	Facilitator
Person months worked:	1.0 month
Contribution to Project:	Delivers intervention to study participants
Funding support:	This award

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

GEWIRTZ, Abigail

Current Support

Title: Midwest Continuum of Care for Child Trauma (PI)

ID#: U79 SM056177

Period: 12/30/2005 – 9/29/2016

Effort: 50%

Funding:

Supporting agency & contact:

DHHS SAMHSA

Cicely Burrows-McElwain, Program Official

cicely.burrows-mcelwain@samhsa.hss.gov

Goals/Specific Aims: The goals of this project are to 1) improve access to trauma-informed practices and treatment for traumatized children and families; 2) implement and sustain evidence-based trauma treatment models in the Upper Midwest; and 3) build and maintain consensus for child trauma.

Title: Evaluation of TF-CBT Learning Collaborative (PI)

ID#: 56797

Period: 2/7/2013 – 12/31/2016

Effort: 1%

Funding:

Supporting agency & contact:

Minnesota Department of Human Services

Patricia Nygaard, pat.nygaard@state.mn.us

Goals/Specific Aims: The purpose of this contract is to provide evaluation of training and consultation efforts to expand within the mental health provider community the clinical capacity to provide Trauma-Focused Cognitive Behavioral Therapy.

Title: Evaluation of the Sesame Street for Military Families: Transitions Program

ID#: NA

Period: 1/22/2016 – 12/31/2016

Effort: 5%

Funding:

Supporting agency & contact:

Sesame Workshop

David Cohen, david.cohen@sesame.org

Goals/Specific Aims: The goal of this project is to assess parental and child response to the Sesame Workshop's Military Families: Transitions Program.

Change: This is a new active grant.

Recently Completed Support

Title: Effectiveness of a Web-enhanced Parenting Program for Military Families (PI)

ID#: R01 DA030114

Period: 7/15/2010 – 6/30/2016

Effort: 5%

Funding:

Supporting agency & contact:

National Institutes of Health

Belinda Sims, Program Official, bsims@nida.nih.gov

Goals/Specific Aims: The overarching goal of this study is to advance research on family-based substance use prevention for reintegrating OEF/OIF personnel by examining whether an Oregon Parent Management Training (PMTO) prevention intervention, enhanced with e-technology and adapted for combat-deployed families' needs, will reduce risk behaviors associated with youth substance use by improving parenting, child, and parent adjustment. Specific aims are 1) examine the usability and feasibility of an adapted PMTO prevention program: After Deployment Adaptive Parenting Tools (ADAPT); 2) assess effectiveness of ADAPT program compared with a services-as-usual comparison group among 400 reintegrating MN Army National Guard families with 6-12 year old children; and 3) detail and describe responsiveness to intervention.

Title: DCISR for Adaptive Intervention Models in Children's Mental Health (Co-I)

ID#: P20 MH085987

Period: 8/24/2010 – 6/30/2016

Effort: 5%

Supporting agency & contact:

National Institutes of Health

Title: Preventing Military Post-Deployment Adjustment Problems: Key Family Processes (Sub PI)

ID#: R21 DA034166

Period: 5/1/2013 – 4/30/2016

Effort: 10%

Funding: Wichita State University (prime

Supporting agency & contact:

funding source: NIH)

Fran Cook, WSU Research Administrator,

researchcontracts@wichita.edu

Goals/Specific Aims: Dr. Gewirtz's portion of this project is to develop a micro-social family interaction coding system and macro-level family interaction rating systems, applying her experience and knowledge in the family interaction of individuals who have experienced trauma and in the family interaction of military service members during post-deployment periods.

Title: ADAPT: After Deployment Adaptive Parenting Tools (Sub PI)
ID#: R44 HD066896 *Period:* 10/1/2013 – 10/31/2015
Effort: 5% *Funding:* (no cost extension) IRIS Media
Supporting agency & contact: (prime funding source: NIH)
 Joanne Dwinell, Business Manager, jdwinell@irised.com
Goals/Specific Aims: The goal of this Phase II project, ADAPT Online (After Deployment: Adaptive Parenting Tools), is to strengthen family functioning and improve child outcomes in reintegrating military families. By developing an empirically supported, standalone, web-based parenting intervention for military families with school-aged children, we expect to strengthen parenting practices in families and prevent behavioral and emotional maladjustment in children.

What other organizations were involved as partners?

Organization Name:	University of Michigan
Location of Organization:	Ann Arbor, MI
Partner's contribution to the project:	Collaboration
Organization Name:	University of Oregon
Location of Organization:	Eugene, OR
Partner's contribution to the project:	Collaboration
Organization Name:	IRIS Media, Inc.
Location of Organization:	Eugene, OR
Partner's contribution to the project:	Collaboration
Organization Name:	Implementation Sciences International, Inc.
Location of Organization:	Eugene, OR
Partner's contribution to the project:	Collaboration

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: Not applicable

QUAD CHARTS: See attached

9. APPENDICES:

Recruitment graph

The following materials are available upon request:

- Online questionnaire for baseline data collection (9 pages)
- Online parent survey for time point 1 (69 pages)
- ADAPT4U facilitator curriculum manual (300 pages)
- Access to ADAPT4U online program

Comparing Web, Group, and Tele-health Formats of a Military Parenting Program

Log Number: NH13001 - EDMS 5832

W81XWH-14-1-0143



PI: Dr. Abigail Gewirtz

Org: University of Minnesota

Award Amount: \$3,051,363

Study/Product Aim(s)

Specific Aim 1: Conduct a three-group, two-site randomized trial to test the comparative effectiveness of ADAPT delivery approaches.

Specific Aim 2: Test the generalizability of ADAPT effectiveness across three delivery approaches using intent to treat (ITT) analyses.

Approach

The study will randomly allocate 360 NGR families to one of three conditions: (i) group-based web-enhanced ADAPT; (ii) individualized web-facilitated ADAPT; or (iii) self-directed web ADAPT. Families, with a child aged 5-12, will be enrolled if one parent has deployed to OEF or OIF. Families will complete a pre-intervention baseline (BL) assessment. Families will complete post-intervention follow-up assessments at 6, 12, and 24 months.

We will test the value-added impact of group-based delivery relative to facilitated and self-directed web approaches. Comparative effectiveness will be tested by specifying a non-equivalence hypothesis from group-based and individualized facilitated relative to self-directed web only.



Preliminary results suggest that ADAPT is feasible, acceptable, and associated with improvements in parenting, couple adjustment, and emotional awareness. Thus, we have experience engaging both military parents.

Timeline and Cost

Activities	CY	14-15	15-16	16-17	17-18	18-19
Prepare IRB/DOD regulatory documents Recruit and staff open positions Modify ADAPT delivery format						
Recruit and randomize participants						
Complete baseline and subsequent participant assessments						
Conduct outcome data cleaning and analysis						
Examine differential effectiveness						
Estimated Budget		\$255,831	\$536,315	\$856,129	\$714,963	\$688,125

Goals/Milestones

CY14 Goal –Project Preparation

- ☒ Obtained IRB/DOD approval
- ☒ Hire project staff- Staffed Key study personnel
- ☒ Modified ADAPT curriculum and delivery format
- ☒ Test ADAPT curriculum for usability- Piloted ADAPT curriculum for usability

CY15 Goal – Recruit and Randomize Participants

- ☒ Participants recruitment commenced June 18, 2015
- ☒ Commenced baseline assessment on enrolled families

CY16 Goal –Conduct Randomized Control Trial

- ☒ Deliver ADAPT group with fidelity
- ☒ Interventions commenced January 2016

CY 17 Goal – Conduct participant assessments

- ☐ Assess adult adjustment, observational parenting, child and couple measures

CY 18 Goal - Data Cleaning and Analysis

- ☐ Create data management structure to organize, clean and analyze data

CY19 Goal – Examine differential effectiveness

- ☐ Begin outcome data cleaning and analysis

Comments/Challenges/Issues/Concerns

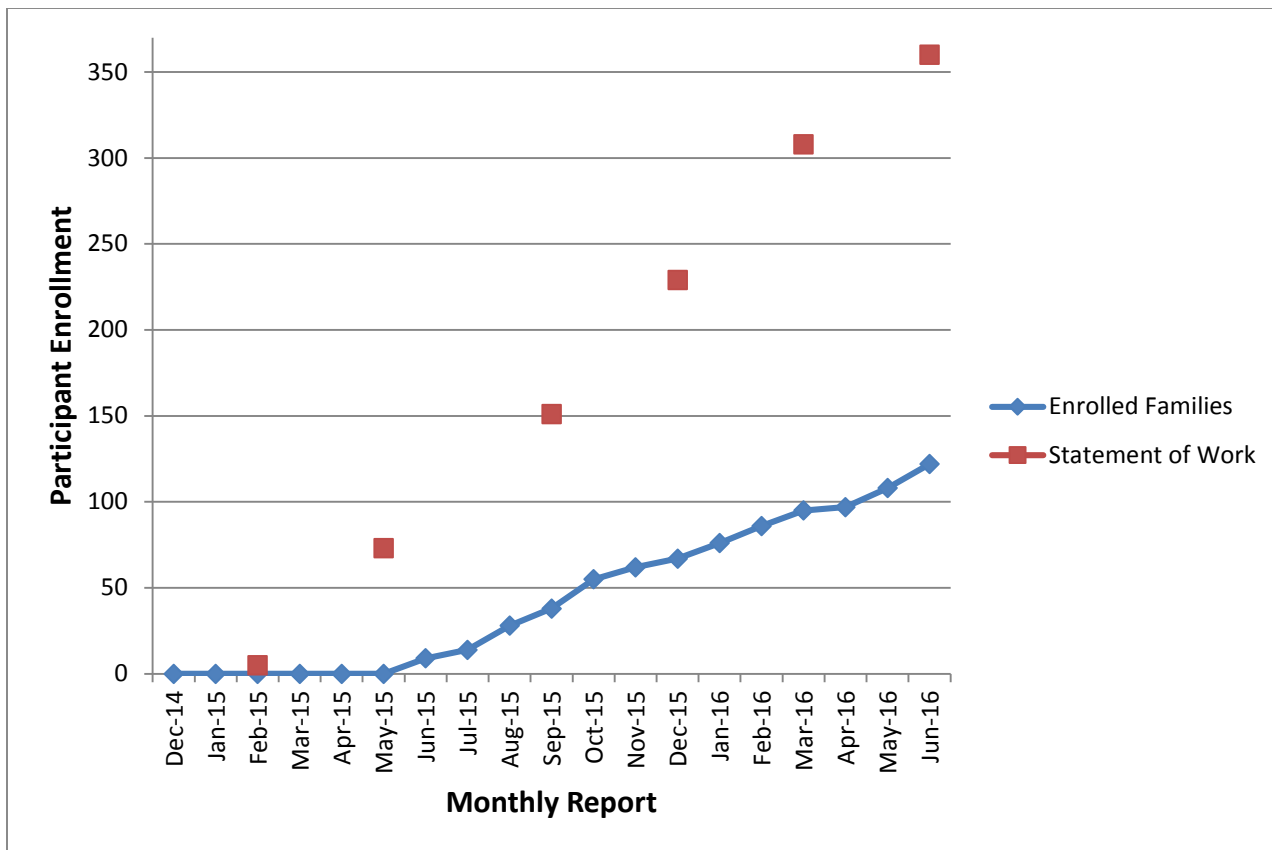
Budget Expenditure to Date

Amount spent in Y2 Q4 (3/1/16 – 5/31/16): \$106,478 total cost

Amount spent in Y2 (6/1/15 – 5/31/16): \$536,315 total costs

Amount spent to date (6/1/14 – 5/31/16): \$792,146 total costs

Updated: June 23, 2016



Note. 260 individuals have clicked on eligibility survey; 242 individuals have begun the eligibility survey.

Plan for Michigan recruitment was submitted to and reviewed by DOD June 2016.

Estimated 110 families delayed in enrolling due to deployment, age of child, scheduling conflicts, etc.